## 510(k) SUMMARY

## Flower Bone Screw Set

**Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared**

Flower Orthopedics Corporation
7715 Crittenden Street, #413
Philadelphia, PA 19118

Phone: (267) 437 3063
Facsimile: (267) 437 3072

OCT 30 2013

Contact Person: Oliver Burckhardt, Chief Executive Officer
Date Prepared: October 29, 2013

**Name of Device and Name/Address of Sponsor**

Flower Bone Screw Set

**Common or Usual Name/Classification Name**

Bone Fixation Screw

Product Codes: HWC; HTN (Orthopedic Review Panel)

Product Classifications: 21 C.F.R. 888.3040 - Smooth or Threaded Metallic Bone Fixation Fastner; 21 C.F.R. 888.3030 - Single/multiple component metallic bone fixation appliances and accessories

**Predicate Devices**

Medical Facets Bone Fixation Screws and Pins (K112727)
Howmedica Asnis Micro Cannulated Screw (K071092)
Treu Bone Fixation Screws and Pins (K083912)
Synthes 4.5mm and 6.5mm Headless Compression Screws (K080943)
Flower Small and Medium Implant Set (K123562)

**Intended Use / Indications for Use**

The Flower Bone Screw set is intended to be used for the fixation of bone fractures, fusion of joints or bone reconstruction.

**Device Description**

The Flower Bone Screw Set consists of the following components and accessories: solid, cannulated, and headless compression screws, as well as washers, all made of a titanium alloy compliant with ASTM F136. The device is provided with general purpose instruments.

**Technological Characteristics**

The Flower Bone Screw Set consists of the following components/configurations:

- Cannulated Bone Screws with a diameter range of 2.0-7.3mm and a length range of 10.0-130.0mm;
- Solid Bone Screws with a diameter range of 2.0-4.5mm and a length range of 10.0-70.0mm; and
- Headless Compression Bone Screws with a 6.5mm diameter and a length range of 45.0-130.0mm.

**Performance Data**

The Flower Bone Screw Set was tested (worse case) according to the following standards:

- ASTM F136, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401);
- ISO 7153-1, Surgical instruments – Metallic materials – Part 1: Stainless steel (ISO 7153-1:1991, including Amendment 1:1999); German version EN ISO 7153-1:2000;
- ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process;
- ISO 10993-5, Biological evaluation of medical devices – Part 5: Tests for *in vitro* cytotoxicity;
- ISO 11137-1, Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices. (Sterility)

In addition, an engineering analysis has been performed to demonstrate that the Flower Orthopedics cannulated, solid and headless compression bone screws provide appropriate mechanical strength for the claimed intended use.

In all instances, the Flower Bone Screw Set functioned as intended and test results, as well as an engineering analysis, demonstrate substantial equivalence with the cited predicate devices.

**Substantial Equivalence**

The Flower Bone Screw Set is substantially equivalent to the identified predicate devices. The subject devices have the same intended uses /indications, technological characteristics, and principles of operation as its predicate devices. An engineering analysis was performed to demonstrate that the Flower Orthopedics cannulated, solid and headless compression bone screws provide appropriate mechanical strength for the claimed intended use. Thus, the subject bone screws are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 30, 2013

Flower Orthopedics Corporation
% Ms. Janice M. Hogan
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Re: K132248
Trade/Device Name: Flower Bone Screw Set
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, HTN
Dated: September 18, 2013
Received: September 18, 2013

Dear Ms. Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin FD Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Indications for Use Statement**

510(k) Number (if known): K132248

Device Name:

Indications for Use:

The Flower Bone Screw Set is intended to be used for the fixation of bone fractures, fusion of joints or bone reconstruction.

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|---|---|---|
| Prescription Use ___X___<br>(Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____<br>(21 CFR 801 Subpart C) |

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices